NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY, Plaintiff, v. ACTAVIS ELIZABETH LLC, GLENMARK PHARMACEUTICALS INC., SUN PHARMACEUTICAL INDUSTRIES LTD., SANDOZ INC., MYLAN PHARMACEUTICALS INC., APOTEX INC., AUROBINDO PHARMA LTD., TEVA PHARMACEUTICALS USA, INC., SYNTHON LABORATORIES, INC., ZYDUS PHARMACEUTICALS, USA, INC., Defendants.	**Hon. Dennis M. Cavanaugh** **OPINION** Civil Action No. 07-cv-3770 (DMC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon motion by Defendants Sun Pharmaceutical Industries LTD., Actavis Elizabeth LLC, Glenmark Pharmaceuticals Inc., Sandoz Inc., Mylan Pharmaceuticals Inc., Apotex Inc., Aurobindo Pharma LTD., Teva Pharmaceuticals USA, Inc., Synthon Laboratories, Inc., Zydus Pharmaceuticals, USA, Inc., ("Defendants") for partial summary judgment regarding no direct infringement pursuant to FED. R. CIV. P. 56(c). After carefully considering the submissions of the parties, and based upon the following, it is the finding of this Court that Defendants' motion for partial summary judgment as to no direct infringement is **granted**.

I. BACKGROUND

Plaintiff Eli Lilly and Company ("Lilly") developed and now markets STRATTERA® brand atomoxetine capsules. In developing STRATTERA Lilly sought a method of treatment patent. On August 19, 1997, U.S. Patent No. 5,658,590 (the "'590 Patent"), titled "Treatment of Attention-Deficit/Hyperactivity Disorder" was issued to John H. Heiligenstein and Gary D. Tollefson and assigned to Lilly. The '590 Patent contains 16 claims. Claim 1 is the only independent claim and it reads "[a] method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine."[1] Claims 2-16 depend on Claim 1 and recite more particular methods of treating ADHD.

Notably, the '590 Patent claims do not and could not include tomoxetine. Indeed, the specification fully acknowledges that tomoxetine is "a well-known drug," which has long been in the public domain. All claims of the '590 Patent require tomoxetine to be administered to (1) a patient in need of treatment and (2) in a so-called "effective" dose. Recognizing that medical judgment and a medical license are required to practice the claimed methods, the patent specification states that the dose administered to the patient "must be set by the physician in charge of the case."

Lilly's action is based on each Defendant's submission of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of atomoxetine before the '590 Patent expires. Lilly initiated this action for patent infringement under 35 U.S.C. § 271(e)(2)(A). Lilly additionally pled conditional grounds for patent infringement under 35 U.S.C. §§ 271(a), (b), and/or (c) should the FDA at some future point approve the ANDAs. Lilly concedes that no such commercialization has begun and the scope of such additional infringement is speculative.

[1] Tomoxetine is now known as atomoxetine.

On April 1, 2008, Defendant Sun Pharmaceutical Industries LTD ("Sun") filed a letter with the Court requesting permission to file a motion for partial summary judgment dismissing Lilly's claim of direct patent infringement under 35 U.S.C. §271(a), and any corresponding claims under 35 U.S.C. §271(e)(2). At the instruction of the Court, throughout the months of May and June the parties attempted to resolve this issue but were unsuccessful. Accordingly, Sun now brings this motion for partial summary judgment. Defendants Actavis Elizabeth LLC, Sandoz, Inc., Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., Apotex, Inc., and Aurobindo Pharma Ltd. all join in this motion.

II. STANDARD OF REVIEW

Summary judgment is granted only if all probative materials of record, viewed with all inferences in favor of the non-moving party, demonstrate that there is no genuine issue of material fact and that the movant is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 330 (1986) (Brennan, J. Dissenting); Fed. R. Civ. P. 56(c). The moving party bears the burden of showing that there is no genuine issue of fact. See id. "This burden has two distinct components: an initial burden of production, which shifts to the non-moving party if satisfied by the moving party; and an ultimate burden of persuasion, which always remains on the moving party." Id. The non-moving party "may not rest upon the mere allegations or denials of his pleading" to satisfy this burden, but must produce sufficient evidence to support a jury verdict in his favor. Id. at 322; see also Fed. R. Civ. P. 56(e); Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). "[U]nsupported allegations in [a] memorandum and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). "In determining whether there are any issues of material fact, the Court must resolve all doubts as

to the existence of a material fact against the moving party and draw all reasonable inferences – including on issues of credibility – in favor of the nonmoving party." Newsome v. Admin. Office of the Courts of the State of N.J., 103 F. Supp. 2d 807, 815 (D.N.J. 2000), aff'd, 51 Fed. Appx. 76 (3d Cir. 2002) (citing Watts v. Univ. of Del., 622 F.2d 47, 50 (D.N.J. 1980)).

III. DISCUSSION

Lilly contends that each of the Defendants' act of filing an ANDA constitutes infringement under 35 U.S.C. § 271(e)(2)(A). Lilly further contends that the Defendants intend to commercialize generic atomoxetine products defined in their ANDAs if they receive FDA approval. Lilly argues that the commercialization of generic atomoxetine before the expiration of the '590 Patent would constitute further infringement of the '590 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c). Defendants assert that Lilly's patent is for the treatment of patients by physicians which is something the Defendants do not do. Defendants further argue that 35 U.S.C. § 271(e)(2)(A) does not create a new or independent infringement test. Based upon these arguments, Defendants proffer that they did not and cannot infringe Lilly's patent.

A. Infringement Under 35 U.S.C. § 271(e)(2)(A)

Subsection 271(e)(2)(A) of the Hatch-Waxman Act "provides an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003). This provision of the Act is about ripeness and establishing jurisdiction. It is well settled that "the substantive determination whether actual infringement or inducement will take place is

determined by traditional patent infringement analysis, just the same as it is in other infringement suits." Id. Thus, while filing an ANDA is sufficient to trigger an action under 35 U.S.C. § 271(e)(2), this subsection "does not determine the ultimate question whether what will be sold will infringe any relevant patent." Glaxo, Inc. v. Novopharm, Inc., 110 F.3d 1562, 1569 (Fed. Cir. 1997).

Plaintiffs contend that the filing of an ANDA in and of itself can be an infringing act. This is an oversimplification of the above outlined standard. The essential "inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists." Id. at 1570. In addressing Lilly's argument that it can establish infringement under 35 U.S.C. § 271(e)(2), Defendants point to the fact that Lilly must still establish that infringement exists. Defendants contend that Lilly cannot establish infringement under 35 U.S.C. § 271(e)(2) for the same reasons that Defendants argue infringement does not exist under 35 U.S.C. § 271(a), which is that none of the Defendants are doctors, they do not treat patients, and they do not prescribe medicines.

B. Infringement Under 35 U.S.C. § 271(a)

Lilly asserts that Defendants directly infringed upon the '590 Patent. To substantiate this claim Lilly has the burden of establishing that Defendants' products infringe each asserted claim of the '590 patent. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000). Proving "[l]iteral infringement requires that the accused device embody every element of the claim." Builders Concrete, Inc. v. Bremerton Concrete Prods. Co., 757 F.2d 255, 257 (Fed. Cir.

1985); Zelinski v. Brunswick Corp., 185 F.3d 1311, 1316 (Fed. Cir. 1999). "If any claim limitation is absent from the accused [method], there is no literal infringement as a matter of law." Bayer, 212 F.3d at 1247. The nature of the invention is important when attempting to prove infringement because there is a clear distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process or method, which consists of a series of acts or steps. See In re Kollar, 286 F.3d 1326, 1332 (Fed. Cir. 2002). Therefore, under 35 U.S.C. §271(a), "[a] method claim is directly infringed only by one practicing the patented method." Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 775 (Fed. Cir. 1993). Practicing the patented method means that one must actually perform each step of the claimed method in the United States, without authority of the patent owner. NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1318 (Fed. Cir. 2005); E-Pass Techs., Inc. v. 3Com Corp., 473 F.3d 1213, 1223 (Fed. Cir. 2007).

To prevail on its claim of direct infringement, Lilly must establish that Defendants will practice every step of the patented method, including the central limitation of "administering to a patient in need of ADHD treatment an effective amount of tomoxetine." See Warner-Lambert, 316 F.3d at 1363 (no direct infringement without evidence that a pharmaceutical company "has directly practiced or will ever practice" the method patent by treating patients). Conversely, the mere sale of a product to perform a claimed method does not constitute direct infringement. See, e.g., Joy Techs., 6 F.3d at 774 ("the sale of equipment to perform a process is not a direct infringement of the process"); Mendenhall v. Cedarapids, Inc., 5 F.3d 1557, 1579 (Fed. Cir. 1993) (manufacture and sale of a drum mixer did not directly infringe a method patent that covered the method for preparation of hot mix asphalt)). Likewise, it is not direct infringement to sell a product capable of being used

only in the patented method. See, e.g., Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1310-11 (Fed. Cir. 2006) (rejecting a district court holding that a method claim would be infringed by selling dental position adjustment devices only capable of infringing use); Joy Techs., 6 F.3d at 774-75 ("a method claim is not directly infringed by the sale of an apparatus even though it is capable of performing only the patented method").

In Warner-Lambert, the plaintiff claimed that an ANDA filed by Apotex to market a generic formulation of Warner-Lambert's Neurontin® (gabapentin) infringed Warner-Lambert's method patent claiming a treatment of neurodegenerative diseases by "administering a therapeutically effective amount" of gabapentin. 316 F.3d at 1363. In Warner-Lambert, the Federal Circuit concluded that there was no direct infringement because "there is no evidence in the record that Apotex has directly practiced or will ever practice any of the methods claimed." Id. In reaching this conclusion, based on facts that are identical to the facts at issue in this case, the Federal Circuit explained that the activities of pharmaceutical manufacturers are fundamentally different than prescribing physicians and, therefore, pharmaceutical companies cannot directly infringe such method of treatment claims:

> That is hardly surprising – pharmaceutical companies do not generally treat diseases; rather, they sell drugs to wholesalers or pharmacists, who in turn sell the drugs to patients possessing prescriptions from physicians. Pharmaceutical companies also occasionally give samples of drugs to doctors and hospitals. In none of these cases, however, does the company itself treat the disease.

Id. at 1363 n.7 (emphasis original).

The same rationale applies here, Lilly's claims are method of treatment claims that require "administering to a patient in need of ADHD treatment an effective amount of tomoxetine."

Moreover, the specification requires that tomoxetine be administered by "the physician in charge of the case." Like Apotex in the Warner-Lambert case, Defendants do not diagnose patients and do not administer drugs. Moreover, Lilly has made no allegation that Defendants will employ physicians to prescribe tomoxetine to treat patients with ADHD. As in Warner-Lambert, Defendants will not infringe Plaintiff's patent. Even if Defendants manufacture, market, and sell tomoxetine products, they would not be "using" tomoxetine to treat ADHD. Therefore, because it is indisputable that Defendants do not treat patients or prescribe drugs, no genuine issue of material fact remains and Defendants are entitled to partial summary judgment regarding direct infringement.

IV. CONCLUSION

For the reasons stated, this Court finds that Defendants' motion for partial summary judgment is **granted**. An appropriate Order accompanies this Opinion.

S/ Dennis M. Cavanaugh
Dennis M. Cavanaugh, U.S.D.J.

Date: May 20, 2009
Orig.: Clerk
cc: Counsel of Record
The Honorable Mark Falk, U.S.M.J.
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